

TOBINICK 3.0-013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

J1046 U.S. PRO
09/09/04 05/01
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In re patent application of:
EDWARD L. TOBINICK, M.D.

Serial No. : Group Art Unit
Filed: Examiner
For: CYTOKINE ANTAGONISTS :
FOR THE TREATMENT OF :
LOCALIZED DISORDERS : April 5, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION TO MAKE SPECIAL
(MPEP Section 708.02)

04/09/2001 JBALINAN 00000082 09826976
04 FC:122
130.00 OP

Sir:

Applicant hereby files this Petition to Make Special this application for the purposes of examination and payment of the issue fee, on the grounds of a pre-examination search.

Applicant also submits the petition fee.

The application presents claims directed to a single invention. In case the Examiner believes that there is more than one invention, applicant hereby elects without traverse Claims 1 to 17.

A pre-examination search was made of the records of the U.S. Patent Office by applicant's attorney, Ezra Sutton. The field of search included Class 514, Subclasses 2, 12, 171, 261, 262, 264, 282, 323, 327, and 348; Class 530, Subclasses 324, 350, and 399; Class

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424, Subclasses 158.1 and 810; and Class 435, Subclasses 69.1, 69.52, 69.7, 91.41, and 240.27.

INVENTION SEARCHED

Cytokine antagonists for use in localized clinical disorders are provided for the treatment and prevention of damage to the optic nerve, other cranial nerves, spinal cord, nerve roots, peripheral nerves or muscles caused by any one of the following: a herniated nucleus pulposus, osteoarthritis, other forms of arthritis, disorders of bone, disease, trauma, Alzheimer's Disease, or Postherpetic Neuralgia. The cytokine antagonists are used to treat these disorders by local administration. These cytokine antagonists include antagonists to tumor necrosis factor; interleukin-1; interleukin-6; and interleukin-8.

PATENTS SELECTED IN SEARCH

As a result of the search, we have uncovered the following U.S. patents:

<u>U.S. Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
5,756,482	Roberts et al	
5,574,022	Roberts et al	
5,863,769		
6,013,253		
5,075,222		

PCT Appln WO 00/18409 (4/6/00)

A copy of each patent is enclosed.

DISCUSSION OF SELECTED PATENTS

U.S. Patent Nos. 5,756,482 and 5,574,022 to ROBERTS et al disclose methods of attenuating physical damage to the nervous system and to the spinal cord after injury using steroid hormones or steroid precursors such as pregnenolone, and pregnenolone sulfate in conjunction with a non-steroidal anti-inflammatory substance such as indomethacin. These prior art patents do not teach the use of specific cytokine antagonists for the suppression and inhibition of the action of IL-1 in the human body to treat neurological disease, trauma, injury or compression, as in the present invention.

U.S. Patent No. 5,863,769 discloses using IL-1 RA for treating various diseases. However, it does not disclose administering cytokine antagonists locally for the treatment of localized neurological or muscular disorders.

U.S. Patent No. 6,013,253 discloses using interferon and IL-1 RA for treating multiple sclerosis. However, it does not disclose administering cytokine antagonists locally for the treatment of localized neurological or muscular disorders.

U.S. Patent No. 5,075,222 discloses the use of IL-1 inhibitors for treatment of various disorders. However, it does not disclose administering cytokine antagonists locally for the treatment of localized neurological or muscular disorders.

PCT Application WO 00/18409 (6 April 2000) discloses the use of various medications to treat nerve root injury. It does not disclose the methods discussed herein,

including localized administration, perilesional administration, or intralesional administration, of the substances discussed herein.

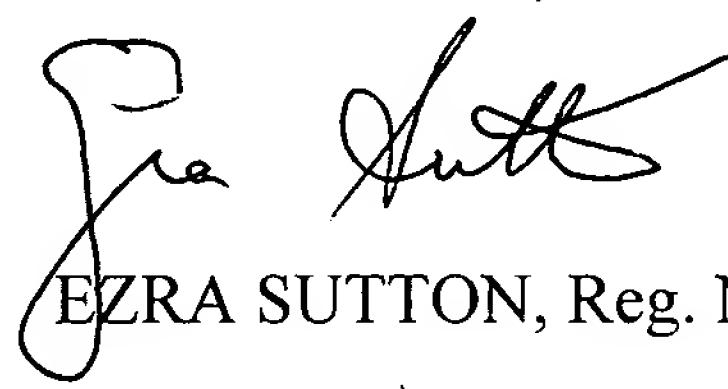
CONCLUSION

None of the prior art patents disclose or teach the use of localized administration of a cytokine antagonist as in the present invention for suppression and inhibition of the action of a specific cytokine in a human to treat localized neurological or muscular disease, in which the cytokine antagonist provides the patient with a better opportunity to heal, slows disease progression, prevents neurological damage, or otherwise improves the patient's health.

The distinctions over the prior art are set forth in the claims, and they patentably distinguish over the prior art. Accordingly, this Petition should be granted.

Respectfully submitted,

EZRA SUTTON, P.A.

A handwritten signature in black ink, appearing to read "Ezra Sutton".

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